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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/652,624 | 08/29/2003 | Thomas Lahey | SYNOR-003B | 1030 |

7590 05/12/2005
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EXAMINER

OWENS, AMELIA A

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/652,624 | LAHEY ET AL. | |
| | Examiner | Art Unit | |
| | Amelia A. Owens | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-37 are pending. Drawings, 5 sheets, were filed with the application. Foreign priority was not claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by several references below. Note X=oxygen.

Kikuchi et al (CA 124:23827) teach species according to the invention. See abstract.
Note RN's 480-40-0; 480-44-4; 491-78-1; 520-28-5 for example. Others appear in the abstract.

^{3278/2}
Takayama et al (CA 129:~~587939~~) teach species according to the invention. See abstract,
note RN 110204-45-0 where R10/R11 form methylenedioxy.

Iinuma et al (CA 101:6890) teach species according to the invention. See abstract, note
RN's 59870-76-7; 60948-17-6.

Bhardwaj et al (89:197277), which teach species according to the invention. See abstract,
not RN's 63934-55-4; 59870-76-7; 60948-17-6.

Pratt et al (CA 19:2341c-i), which teach species according to the invention. See abstract;
RN's 491-70-3; 520-36-5.

^{2485 a-e}
Dieterich (CA 3:~~13552~~), which teach species according to the invention. See abstract;
RN 855-96-9.

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Perkin et al (CA 9:8695), which teach species according to the invention. See abstract; RN491-70-3.

Ludwinowsky et al (CA 1:²²⁰⁷~~2207~~), which teach species according to the invention. See abstract; RN 33554-46-0.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by several references below. Note X=sulfur.

Levai (CA 132:122483), which teach species according to the invention. See abstract; RN's 16074-52-5; 16074-59-2; 82340-44-1 for example.

Varma et al (CA 131:228267), which teach species according to the invention. See abstract; RN's 5465-04-3; 244107-94-6.

Varma et al (CA 130:311380) which teach species according to the invention. See abstract; RN 223594-07-8.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a,b) as being anticipated by Elisei et al (CA 133:119982) which teach species according to the invention. See abstract; RN's 171119-01-0; 284684-01-1; 284684-02-2 for example.

The rejection is being made under 35 USC 102 a,b because it is unclear from the abstract whether the 2000 date is more than a year prior to applicants earliest priority claim.

Claims 2-37 are not included in the rejections as the references do not teach or fairly suggest the claim limitations. For example, claim 2 requires R10/R12 both to be hydroxyl.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is the method of inhibiting T-lymphocyte activity in human or veterinary patient. See claim 10.

The state of the prior art predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant

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case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to any/all diseases whether the inhibition of T-lymphocytes would make a difference in the disease. Hence, in the absence of a showing of a nexus between any and all known diseases and the inhibition of T-lymphocytes, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of T-lymphocyte inhibition in human and/or veterinary patients.

The guidance and working examples: The guidance present in the specification is compounds according to the invention were made. It is not clear whether or not the claimed compounds were tested. See examples 3-10. For example, claim 12 specifically recites that the compound is not luteolin, yet luteolin is referred to in the figure 1 to seemingly demonstrate the efficacy of applicants' invention.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of any disease by inhibiting T-lymphocyte activity. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by inhibition of T-lymphocyte activity using the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 14-18, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 has internal period at page 38 lines 26 and 29, for example.

The claims employ the term 'derivative' which is ambiguous since derivative is referring to material 'derived' from the named formula while applicants' material is the claimed formula. It is recommended that the term 'derivative' be replaced with the term 'compound'.

Claim 35, the term 'analog' is indefinite. Is it functionally similar? Is it structurally close? How close is a structure of a material would be considered an analog? It is recommended that the term be omitted from the claim since a compound is defined by Markush elements and not how analogous it is to the Markush elements.

Claims 14-17, what is a 'congener' of rutin? Is it functionally similar? Is it structurally close?

Claim 18 what is meant by 'undergoes first pass metabolism'? How is this different from the usual meaning of 'metabolism'?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-110 of U.S. Patent No. 6,774,142 B2. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to the same generic concept.

USP 142 B2 teach compounds according to the invention and their use as inhibitors of T-lymphocyte activity. See claims. Note that the variables while not identical overlap significantly.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the USP '142 B2 genus in order to obtain additional beneficial compounds which inhibit T-lymphocyte activity. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of USP '142 B2 in the expectation of obtaining a useful compound to inhibit T-lymphocyte activity as compounds similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

The species claims are included as the genus of the reference includes said species and they are specifically claimed. Compare claims 1-8 of USP '142 B2 with the instant claims 3-10.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

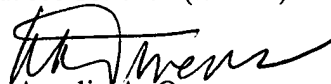
Claim 13 is rejected under 35 U.S.C. 101 because the claims are drawn to multiple active ingredients without naming what the second ingredient is. The second ingredient can have similar activity or completely unrelated activity. Thus the utility of the combination is unknown and unlimited. Since no guidelines can be given to such unlimited method/composition, the claims are wholly inoperable in absence of any give nature of the compound/composition used in the method.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'A. Owens', with a stylized flourish at the end.

Amelia A. Owens
Primary Examiner
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